PARAmed
MEDICAL SYSTEMS

K122034

510(K) Summary

Date 05/07/2012

The following Special 510(k) summary has been prepared pursuant to requirements specified in 21CFR 807.92(c).

DEC 06 2012

Manufacturer Information

Manufacturer:	Paramed Srl
Address:	Corso Perrone 73R 16152 Genova, Italy
Establishment registration number:	3004994584

807.92(a)(1)

Submitter Information

Correspondent:	Richard Olson, Correspondent USA Paramed Medical Systems, Inc 6204 W. Oakton Street Morton Grove, IL 60053 Toll Free: 1 866 840-7565 T 1 847 470-0580nF 1 847 470-0612
Contact Person	Luisella De Benedetti Paramed S.r.l. Corso F.M. Perrone 73R 16152 Genova +39 010 6489 358 luisella.debenedetti@paramed.it

807.92(a)(2)

Trade Name:	MrJ 3300
Common Name:	Magnetic resonance diagnostic system
Classification Name(s):	System, Nuclear Magnetic Resonance Imaging
Classification and class of device:	21 CFR 892.1000, class II
Classification Number:	90LNH

807.92(a)(3)

Predicate Devices

Paramed	MrJ	K033507
Paramed	MrJ Inspire	K100164
Paramed	MrOpen 05T	K101295
Paramed	Performance Package	K121249

68/245

807.92(a)(4)

The MrJ 3300 is a magnetic resonance imaging device characterized by an open structure to minimize claustrophobic reactions. The magnet is a permanent "C" shaped joke designed to minimize the installation area and the Controlled Access area in order to fit also very small hospital and clinics.

It is indicated for use as a diagnostic imaging device that produces transverse, sagittal, coronal and oblique cross-sectional images that display the internal structure of the following joints: hip, knee, ankle, foot, shoulder, elbow, wrist, hand, calf, thigh, arm, forearm, Temporo Mandibular Joint (TMJ), C-spine, L-Spine with limitation to joint pathologies (no tumors, no angiography).

The images produced reflect the spatial distribution of protons (hydrogen nuclei) exhibiting magnetic resonance.

The MR parameters that determine image appearance are proton density, spin-lattice relaxation time (Tl), spin-spin relaxation time (T2), chemical shift and flow velocity. When interpreted by a trained physician, these images can yield information that can be useful in the determination of a diagnosis.
The MrJ 3300 has a 0,3 T magnet, which has a higher intensity than the predicate one (0,2T). Of course the new 0,3 T magnet with slightly different dimensions needs a new design of covers and some modest upgrades due to design ageing of the MrJ Inspire 01-2000-01 product.
New covers of the system have been designed by the same company which designed MRJ Inspire's covers and they have been manufactured using the same C-UL-US approved fire protection materials.
The MrJ 3300 employs both the positioning LED (K033507) and the positioning touch screen (K100164) to give to the user the maximum chances to get rapidly to the correct patient positioning.
The scanning sequences are the same employed in MrJ Inspire model (K100164) unless the FLAIR sequences which are equivalent to the same FLAIR sequences employed on the MrOpen 05 T K101295 device.

The MrJ 3300 is furnished with the Performance Package of new concept receiving coils (code 06-0096-00) equivalent to the Performance Package K121249.

807.92(a)(5)

Device Intended Use(s)

The intended use of Paramed's MrJ 3300 product is the same than the intended use of the predicate one: it is indicated for use as a diagnostic imaging device that produces transverse, sagittal, coronal and oblique cross-sectional images of hip, knee, ankle, foot, shoulder, elbow, wrist, hand, calf, thigh, arm, forearm, Temporo Mandibular Joint (TMJ),C-spine, L-Spine with limitation to joint pathologies (no tumors, no angiography).
The device produces transverse, sagittal, coronal and oblique cross-sectional images, displaying the internal structure of the limbs and joint being imaged. The images that are produced correspond to the spatial distribution of protons (hydrogen nuclei) that check the magnetic resonance properties and depend upon the MR parameters (spin-lattice relaxation time (T1), spin-spin relaxation time (T2), nuclei density, flow velocity and chemical shift). If interpreted by a medical expert, these images can provide diagnostically useful information.

807.92(a)(6)

Technological Characteristics

The MrJ 3300 MRI system is substantially equivalent to:

- Paramed Mr Inspire K033507 for intended use, architecture, software and positioning LED system.
- Paramed Mr Inspire K100164 for intended use, covers' materials, and Touch panel positioning system.
- Paramed MrOpen 05T K101295 for the FLAIR sequences
- Paramed Performance Package K121249 (C-Spine coil, L-Spine coils, MP_wrap coil) complete equivalence except the working frequency which here is centered at 13 MHz due to the higher magnetic field.

Neither the intended use nor the technological characteristics of this model differ from those of the referenced models. A table is supplied later on regarding design similarities.

70/?35

807.92(b)(1)

The discussion of the nonclinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence.

The nonclinical tests are summarized in this submission.

The aim of the nonclinical test is to demonstrate performance towards the relevant standards listed in form 3514.

Parameter	MrJ 3300	MrJ Inspire with Extended Kit K100164
IEC 60601-1 Electrical safety	Conform	Conform
IEC 60601-1-2 Electromagnetic compatibility	Conform	Conform
IEC 60601-1-4 Programmable devices	Conform Sw release n.1.A.3	Conform Sw release n. 1.A.3
IEC 60601-2-33 Operation mode	Normal Controlled Operation Mode	Normal Controlled Operation Mode
IEC 60601-2-33 SAR *Whole Body* *Head* *Exposed Body*	Conform *0.66 +/- 0.10 W/Kg* *0.9 +/- 0.6 W/Kg* *0.66 +/- 0.10 W/Kg*	Conform 0,57 +/- 0,15 W/Kg - -
IEC 60601-2-33 max dB/dt	Conform 19,8 T/s with τ = 600 µs Gradient coil diameter 850 mm	Conform 19,8 T/s with τ = 600 µs Gradient coil diameter 850 mm
IEC 60601-2-33 max Acoustic noise Level A-weighted L eq	Conform (<99dBA) 89.8 +/- 0.5 dBA	Conform (<99dBA) 79.0 +/- 0.1 dBA
IEC 60601-2-33 max Acoustic noise Peak	Conform (<140 dB) (102.5 +/- 0.5) dB	Conform (<140 dB) 82.0 +/- 0.1 dB
NEMA MS-1 SNR multichannel coils	Conform see Laboratory testing for the results	Conform
NEMA MS-3 Image uniformity	Conform see Laboratory testing for the results	Conform
NEMA MS-1 SNR for single channel coils	Conform see Laboratory testing for the results	Conform
NEMA MS-2 Geometric Distortion	*Conform see Appendix L*	*Conform*
NEMA MS-5 SLICE THICKNESS	*Conform see Appendix L*	*Conform*

The non clinical test demonstrate that the new tomograph respects the standards as the previous models did.

Differences in the results are due to the new magnet adopted by this model.

ADDED PAGE 70356/295

807.92(b)(2)

A brief discussion of the clinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence. This discussion shall include, where applicable, a description of the subjects upon whom the device was tested, a discussion of the safety or effectiveness data obtained from the testing, with specific reference to adverse effects and complications, and any other information from the clinical testing relevant to a determination of substantial equivalence.

The proposed images (see clinical output par.) are clinically acceptable as those presented for the same districts in previous 510 (k) files to which equivalence is claimed.

Coil	**Limb**	**Standard/Optional coils available with MrJ 3300 confronted with corresponding coils available on MrJ Inspire K100164 system**
Knee	Knee	Equivalent
Hip	Hip	Equivalent
Hand	Hand	Equivalent
Shoulder	Shoulder	Equivalent
TMJ	TMJ	Equivalent
Knee large	Knee large	Equivalent
VS	Hand	Equivalent
VL	Thigh	Equivalent
VXL	L-Spine small dimensions' patient	Equivalent
C-Spine	C-Spine	Equivalent
L-Spine small	L-Spine on small patient	Equivalent
L-Spine Large	L-Spine on big patient	Equivalent
MP_Wrap	Knee	Equivalent

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Sequence used with MrJ3300	Sequence used with MrJ Inspire K100164	District	Decision with reference to MrJ Inspire
SCOUT	SCOUT	Knee	Equivalent
SE	SE	Knee	Equivalent
E-RASE	E-RASE	Hand	Equivalent
DE	DE	Knee	Equivalent
GFE	GFE	Knee	Equivalent
STIR	STIR	Knee	Equivalent
STIR GFE	STIR GFE	Knee	Equivalent
SE T2	SE T2	Hand	Equivalent
3D GFE	3D GFE	Hand	Equivalent
3D GFE SPOILED	3D GFE SPOILED	Knee	Equivalent
3D GFE EMIT	3D GFE EMIT	Knee	Equivalent
3D GBASS	3D GBASS	L-Spine	Equivalent
RISE T2	RISE T2	Hand	Equivalent
RIDE	RIDE	Shoulder	Equivalent
FAST RISE	FAST RISE	C-Spine	Equivalent
FIR	FIR	L-Spine	Equivalent
FWS GFE	FWS GFE	Knee	Equivalent

Sequence used with MrJ3300	Sequence used with MrOpen 05T K101295	District	Decision with reference to MrOpen 05T
FLAIR T1	FLAIR T1	C-Spine	Equivalent
FLAIR T2	FLAIR T2	C-Spine	Equivalent

807.92(b)(3)

The conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device identified in paragraph (a)(3) of this section.

On the basis of the internal final inspection data reports, summarized in the above 807.92(b)(1) and (b)(2) point and of the test images performed both on phantoms and on healthy volunteers, we declare that the MrJ 3300 device is at least as safe and effective as the predicate devices.

K71295

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Paramed Srl
% Ms. Luisella De Benedetti
Quality Manager
Paramed Srl
Corso F.M. Perrone 73R
16152 Genova, Italy

December 6, 2012

Re: K122034
Trade/Device Name: MrJ 3300
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: November 14, 2012
Received: November 19, 2012

Dear Ms. De Benedetti:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael D. O'Hara

Janine M. Morris, M.S.
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: MrJ 3300 code 06-2000-00

Indications for Use:

The MrJ 3300 is indicated for use as a diagnostic imaging device that produces transverse, sagittal, coronal and oblique cross-sectional images that display the internal structure of the following joints: hip, knee, ankle, foot, shoulder, elbow, wrist, hand, calf, thigh, arm, forearm, Temporo Mandibular Joint (TMJ), C-spine, L-Spine with limitation to joint pathologies (no tumors, no angiography).

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Michael D. O'Hara

(Division Sign-Off)
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety

510(k) Number K122034